K051376

AUG 2 3 2005

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250

Contact Person: Jennifer Tribbett

Date Prepared: May 25, 2005

2) Device name

Proprietary name: AccuChek® Instant Plus Dual Testing System
Common name: Glucose and Cholesterol
Classification name: Glucose Oxidase, Glucose and Enzymatic Esterase-Oxidase, Cholesterol.

3) Predicate device

The AccuChek Instant Plus Dual Testing System is substantially equivalent to the AccuChek Instant Plus System described in both K944458 and K944459.

4) Device Description

The AccuChek Instant Plus system had each parameter (cholesterol and glucose) cleared separately. Since the device can use either the glucose test strip or the cholesterol test strip, the agency considers this dual testing system a new device which requires data to prove that users can distinguish between the two test strips.

The AccuChek Instant Plus Dual Testing System has not been modified. The performance data for the individual test strip type can be found in the following 510(k) submissions:

AccuChek Instant Plus Cholesterol Test Strip: K944458

AccuChek Instant Plus Glucose Test Strip: K944459

In addition, the agency's request does not impact the performance data submitted in the previous 510(k) submissions; however, a new additional study was performed to answer the concerns expressed by the agency.

5) Intended use	The AccuChek® Instant Plus Dual Testing System is designed to quantitatively measure cholesterol and glucose in capillary whole blood. The AccuChek Instant Glucose Test Strips are for use in home and professional settings for testing glucose in whole blood. The AccuChek Instant Cholesterol Test Strips are for use by health care professionals and for home use by people with diabetes for cholesterol screening.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 3 2005

Ms. Jennifer Tribbett
Roche Diagnostics Corporation
9115 Hague Road
Indianapolis, IN 46250

Re: k051376
Trade/Device Name: AccuChek Instant Plus Dual Testing System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, CGA, CHH
Dated: May 25, 2005
Received: May 26, 2005

Dear Ms. Tribbett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson

Carol C. Benson, M.A.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051376

Device Name: AccuChek® Instant Plus Dual Testing System

Indications For Use:

The AccuChek® Instant Plus Dual Testing System is designed to quantitatively measure cholesterol and glucose in capillary whole blood. The AccuChek Instant Glucose Test Strips are for use in home and professional settings for testing glucose in whole blood. The AccuChek Instant Cholesterol Test Strips are for use by health care professionals and for home use by people with diabetes for cholesterol screening.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K051376